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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,518	08/05/2003	Kazuaki Yamashita	Q76798	5424
23373	7590	10/18/2005	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			GITOMER, RALPH J	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/633,518	<b>Applicant(s)</b> YAMASHITA ET AL.	
	<b>Examiner</b> Ralph Gitomer	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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The priority documents received 8/5/03 have been entered and claims 1-20 are currently pending in this application. Priority is granted to 8/9/02. No foreign search report is found in the file.

Although not claimed, the point of novelty may reside in a lipid determining reagent comprising surfactant that also includes an antioxidant for the function of preventing the surfactant from being oxidized. Present claim 20 also states (in the alternative) the surfactant resists oxidation which is given no weight because no degree of such resistance or conditions are set forth. And most common surfactants such as Triton X-100 resist oxidation. All the other limitations are conventional in this art. In present claim 7 antioxidants are listed, however some of these compounds do not appear to be antioxidants. In claim 11 "natural fat" is queried. Clarification is requested.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 14, 16, 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakanishi.

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Nakanishi (EP 1 046 716 A1) entitled "Methods for Quantitating High Density Lipoprotein Cholesterol" teaches in paragraph 10, the presently claimed surfactants for determining lipids. Also see paragraph 14 for brand names. In paragraph 27 appropriate antioxidants may be included in the reagents or reagent kits.

All the features of the claims are taught by Nakanishi for the same function as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanishi.

Nakanishi (EP 1 046 716 A1) entitled "Methods for Quantitating High Density Lipoprotein Cholesterol" teaches in paragraph 10, the presently claimed surfactants for determining lipids. Also see paragraph 14 for brand names. In paragraph 27 appropriate antioxidants may be included in the reagents or reagent kits.

The claims differ from Nakanishi in that claim 7 specifies what compound the antioxidant may be, claims 8-9 are directed to specific concentration ranges of antioxidant, and claims 10-13 are drawn to assaying for neutral fat and total cholesterol.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to select any known antioxidant for its known function with the expected results in view of Nakanishi who teaches the same reagents and surfacts claimed and that appropriate antioxidants may be included. Regarding the concentration ranges of the antioxidants, the broad ranges presently claimed would be encompassed by the teachings of Nakanishi. No novelty is seen in the claimed concentration ranges. Regarding determining LDL, Nakanishi teaches determining HDL and from that, LDL may be determined.

Claims 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Nakanishi in view of Hotta.

The claims differ from Nakanishi in the enzyme reagents to determine HDL and LDL include NAD.

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Hotta (US 2003/0017523 A1) entitled "Method of Measuring Lipid Components and Method of Examining of Renal Failure" teaches in paragraph 57, determining neutral fat with glycerol kinase and glycerol-3-phosphate dehydrogenase, NAD and NADH is measured. Paragraph 59 is directed to total cholesterol. In Example 1, Reagent 1 contains Triton X-100, NAD, dehydrogenase and esterase. In paragraph 18, the method can be used to measure lipid components.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to employ the reagents of Hotta in the method of Nakanishi because there are a number of well known pathways employed to determine both HDL and LDL and to select any of the known reagents to perform these known assays with the expected results would have been obvious. Hotta teaches the presently claimed reagents with the same surfactants for the same function as claimed. No novelty is seen in the presently claimed selection of reagents for determining HDL or LDL.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 17 "an LDL reaction inhibitor" is not understood in context because there is no LDL reaction.

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

DeMagno (US 2005/0032141 A1) teaches determining HDL.

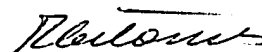
Yagi (US 2005/0027060 A1) teaches in paragraph 21 the presently claimed surfactants.

Esders (4,275,152) teaches the same surfactants as presently claimed for the same function.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ralph Gitomer  
Primary Examiner  
Art Unit 1655

RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200